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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/469,637

12/22/99

MOSES

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CMZ-083CPCN

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BOSTON MA 02109

HM12/0205

EXAMINER

GITOMER, R

ART UNIT

PAPER NUMBER

1623

10

DATE MAILED:

02/05/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/469,637**

Applicant(s)  
**Moses et al.**

Examiner  
**Ralph Gitomer**

Group Art Unit  
**1623**



☒ Responsive to communication(s) filed on Dec 27, 1900

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-121 is/are pending in the application.

Of the above, claim(s) 35-46, 49, 56-63, and 104-121 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-34, 47, 48, 50-55, and 64-103 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's election without traverse of Group I, claims 1-34, 47, 48, 50-55, 64-103 in Paper No. 9 is acknowledged.

5 The nonstatutory double patenting rejection is based on a  
judicially created doctrine grounded in public policy (a policy  
reflected in the statute) so as to prevent the unjustified or  
improper timewise extension of the "right to exclude" granted by  
a patent and to prevent possible harassment by multiple  
assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.  
10 Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.  
1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);  
*In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re*  
*Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15 A timely filed terminal disclaimer in compliance with 37  
CFR 1.321(c) may be used to overcome an actual or provisional  
rejection based on a non-statutory double patenting ground  
provided the conflicting application or patent is shown to be  
commonly owned with this application. See 37 CFR 1.130(b).

20 Effective January 1, 1994, a registered attorney or agent of  
record may sign a terminal disclaimer. A terminal disclaimer  
signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-34, 47, 48, 50-55, 64-103 are rejected under the  
judicially created doctrine of obviousness-type double patenting  
as being unpatentable over claims 1-9 of U.S. Patent No.  
25 6,037,138. Although the conflicting claims are not identical,  
they are not patentably distinct from each other because the  
present claims encompass those of `138.

The claims as presented are not properly searchable, hence  
no art is applied. After the following issues under USC 112 are  
30 considered, a search will be conducted.

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Claims 1-34, 47, 48, 50-55, 64-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while possibly being enabling for specific enzymes and prostate cancer, does not reasonably provide enablement for "a matrix digesting enzyme" or "cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted present claims 7, 69 are directed to cancer of the nervous system and other claims include other tissues, but no such types of cancer are enabled by the present specification.

In claim 1 and all occurrences, "tissue remodeling-associated condition", ~~an enzyme~~, in claim 3 ~~an obstructive condition~~, ~~a degenerative condition~~, in claim 19 and all occurrences, the terms "a prostate disorder-associated enzyme," and "a matrix digesting enzyme," in claim 48 "the enzyme has a molecular weight equal to or greater than approximately 150 kDa", in claim 64 and all occurrences ~~cancer~~, lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which would work in the instant invention.

"Tissue remodeling-associated condition" reads on neurofibromatosis to Wegener's granulomatosis which are unlikely to work in the claimed invention.

¶An enzyme¶ reads on catalase which is unlikely to work in the claimed invention.

¶An obstructive condition¶ reads on a stroke which is unlikely to work in the claimed invention.

5 ¶A degenerative condition¶ reads on Alzheimer's Disease which is unlikely to work in the claimed invention.

"A prostate disorder-associated enzyme" reads on acid phosphatase which is unlikely to work in the claimed invention.

10 "A matrix digesting enzyme" reads on ligninase which will not work in the claimed invention.

"The enzyme has a molecular weight equal to or greater than approximately 150 kDa" reads on innumerable enzymes such as catalase which will not work in the claimed invention.

15 "Cancer" reads on basal cell carcinoma to Ewings sarcoma which are unlikely to work in the claimed invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative disorders and compounds claimed.
- 20 2. Amount of direction or guidance presented is insufficient to predict which disorders and substances encompassed by the claims would work.
3. Presence of working examples are only for specific disorders and substances and extension to other disorders and compounds has  
25 not been specifically taught or suggested.

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4. The nature of the invention is complex and unpredictable.
  5. State of the prior art indicates that most related disorders and substances are not effective for the claimed functions.
  6. Level of predictability of the art is very unpredictable.
  - 5 7. Breadth of the claims encompasses an innumerable number of disorders and compounds.
  8. The level of one of ordinary skill in this art is variable.
- In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

10 Claims 1-34, 47, 48, 50-55, 64-103 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

15 In claim 1, the detecting step implies that something is detected which may or may not be the case. Determining is a more standard term. In claim 48, 81 the MW reads on an infinite weight.

20 The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The Abstract of the Disclosure is objected to because it is not directed to the claimed invention. Correction is required.

25 See M.P.E.P. § 608.01(b).

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The following prior art pertinent to applicant's disclosure is made of record and not relied upon:  
Moses (6,037,138) is the parent case.

5 Any inquiry concerning this communication or earlier  
communications from the examiner should be directed to Ralph  
Gitomer whose telephone number is (703) 308-0732. The examiner  
can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.  
The examiner can also be reached on alternate Mondays. If  
10 attempts to reach the examiner by telephone are unsuccessful, the  
examiner's supervisor, Gary Geist can be reached on (703) 308-  
1701. The fax phone number for this Art Unit is (703) 308-4556.  
Any inquiry of a general nature or relating to the status of this  
application should be directed to the Group receptionist whose  
15 telephone number is (703) 308-1234. For 24 hour access to patent  
application information 7 days per week, or for filing  
applications electronically, please visit our website at  
www.uspto.gov and click on the button Patent Electronic Business  
Center for more information.

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*Ralph Gitomer*  
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Primary Examiner  
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